15. The process of claim 14 wherein, relative to the lactic raw material, the threonine content is reduced by about 15 to 40%, and the aromatic amino acids and tryptophan are increased by about 20 to 60%.

16. The process of claim 14, wherein the treated liquid material is included in an infant or dietetic product as protein raw material.

17. The process of claim 9 wherein the treated liquid material is included in an infant or dietetic product as protein raw material.

18. The process of claim 10 wherein the dried treated liquid material is included in an infant or dietetic product as protein raw material.

19. The process of claim 1 wherein the GMP obtained therefrom includes less than 1% by weight of fat, less than 0.2% by weight of lactose, and less than 3% by weight of true whey products and is included with a carrier in a composition.

20. The process of claim 19 wherein the composition is a pharmaceutical composition containing the GMP as an antithrombotic, antidiarrheal or antibacterial agents.

21. The process of claim 19 wherein the composition is a food composition containing the GMP as an emulsifying, gelling or foaming agent.

22. The process of claim 19 wherein the composition is a dental composition containing the GMP as an agent against plaque and caries.

REMARKS

Claims 1-22 as amended, appear in this application for the Examiner's review and consideration. A marked up copy of the amended claims appears in Exhibit A while a complete set of current claims appears herein in Exhibit B.

Claim 1 has been revised to recite that the process comprises deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5. Claim 11 has been amended to correct an informality. In addition, claims 6 and 9 have been written in independent form, while claims 14-22 have

been amended to be dependent from the process claims. The content of the GMP is also recited in claim 19. As no new matter has been introduced these claim changes should be entered at this time.

The claims have been amended under 35 U.S.C. § 112, first and second paragraphs, for the reasons set forth on pages 2-4 of the action.

In response, claim 11 has been amended as suggested by the Examiner. Also, claim 1 has been amended at least partially as suggested by the Examiner's proposed claim 23a. Part of claim 1 was amended to recite "deionizing the raw lactic material" to more accurately define that step, but the Examiner's proposal of a pH adjusting step was not included, since the deionizing step alone can result in a deionized material having the recited pH (see, e.g., present Example 2). Thus, a pH adjusting step is optional and the independent claims recite this. Accordingly, all rejections based on section 112 should be withdrawn.

As no prior art rejections were made for claims 4 and 6-13, it is believed that the subject matter defined by those claims is allowable. Claims 6 and 9 are written in independent form, so that at least claims 6-7, 9-10 and 17-22 are in condition for allowance.

Claims 1-3 and 5 were rejected as being obvious over U.S. patent 5,434,250 to Shimatani for the reasons set forth on page 5 of the action. Applicants traverse.

Shimatani discloses a process for obtaining sialic acids by acidifying whey to a pH of 2-5 and subjecting the acidified whey to a cation exchanger. The resultant exchanger passed solution can be used as a high sialic acid content composition, or it can be concentrated and/or desalted or dried to a powder (see col. 3, lines 3-7). It is preferred to adjust the pH of the solution to 4 or higher, and then concentrate the solution by evaporation or ultrafiltration. At this pH, the concentration is made using by ultrafiltration using a membrane having a cut off molecular weight of 2,000-50,000 daltons. Alternatively, the concentration can be made by ultrafiltration using an ultrafiltration membrane having a cut off molecular weight of 10,000 at a pH of 4 or lower. This is because Shimatani found that GMP as a sialic acid is present as a monomer at a pH of 4 or lower and associates into a multimonomer at a pH of above 4. The concentrate may be further subjected to ultrafiltration to separate αlactalbumin from the GMP before recovering the GMP.

Shimatani is not relevant to the present claims. As noted above, present claim 1 is directed to a process for extracting GMP by deionizing lactic raw material and then contacting the deionized lactic raw material with an anionic resin to remove GMP from the deionized lactic raw material. The resin with the GMP thereon is separated from the treated liquid and GMP is then obtained by rinsing it from the resin. This is quite different from

Shimatami's recovery of sialic acid from the concentrated, exchanger passed solution. In fact, there is no relation between Shimatami's process and that claimed by applicants, such that all obviousness rejections based on that patent should be withdrawn.

The remaining claims not specifically mentioned above are also patentable over Shimatani. Claims 12-13 recite the preferred steps for recovering GMP from the resin and are patentable as new ways to produce GMP. Claims 14-16 are patentable because they recite new uses for the treated liquid as a protein raw material.

Accordingly, the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested in order to discuss any remaining issues and expedite the allowance of this application.

Finally, a change of address from is enclosed. Please direct all future communications to customer number 28765.

No fee is believed to be due for the claim changes of this response. Please charge any required fees to Winston & Strawn Deposit Account No. 501-814.

Respectfully submitted,

Date: 6/1/01

Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN
200 Park Avenue
New York, New York 10166-4193

(212) 294-6700

APPENDIX A - AMENDED AND NEW CLAIMS

1. A process for the extraction of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing [removing cations from] a lactic raw material for a time sufficient [amount of time] to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material;

separating the resin from the treated liquid material; and

rinsing the resin to obtain the GMP therefrom.

6. A [The] process [according to claim 5] for the extraction of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material, wherein the substantially deionized lactic raw material contacts the resin in a gently stirred reactor at a temperature of less than 50°C for one to ten hours to adsorb the GMP onto the resin;

separating the resin from the treated liquid material; and

rinsing the resin to obtain the GMP therefrom.

9. A [The] process [according to claim 1] for the extraction and removal of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material;

separating the resin from the treated liquid material; and

concentrating the treated liquid material by evaporation and drying.

11. The process according to claim 1 [further comprising,] wherein the anionic resin and the deionized lactic raw material are present in a [volume] ratio by volume of between [about] 1:1 [to about] and 1:30.

14. [A] The [treated liquid material obtained from the] process of claim 1 [and having] wherein the treated liquid material has an amino acid profile is reduced in threonine and enriched in aromatic amino acids and tryptophan relative to the lactic raw material.

15. [A] The process [treated liquid material] of claim 14 wherein, relative to the lactic raw material, the threonine content is reduced by about 15 to 40%, and the aromatic amino acids and tryptophan are increased [to] by about 20 to 60%.

16. [An] The process of claim 14, wherein [infant or dietetic product containing] the treated liquid material [of claim 14] is included in an infant or dietetic product as protein raw material.

17. The [An infant or dietetic product containing the product of the] process of claim 9 wherein the treated liquid material is included in an infant or dietetic product as protein raw material.

18. The [An infant or dietetic product containing the product of the] process of claim 10 wherein the dried treated liquid material is included in an infant or dietetic product as protein raw material.

19. [A glycomacropeptide or caseinoglycomacropeptide ("GMP")] The process of claim 6 wherein the GMP obtained therefrom [the process of claim 1] includes less than 1% by weight of fat, less than 0.2% by weight of lactose, and less than 3% by weight of true whey products and is included with a carrier in a composition.

20. [A] The process of claim 19 wherein the composition is a pharmaceutical composition containing the GMP [glycomacropeptide or caseinoglycomacropeptide ("GMP") of claim 19] as an antithrombotic, antidiarrheal or antibacterial agent[s].

21. [A] The process of claim 19 wherein the composition is a food composition containing the GMP [glycomacropeptide or caseinoglycomacropeptide ("GMP") of claim 19] as an emulsifying, gelling or foaming agent.

22. [A] The process of claim 19 wherein the composition is a dental composition containing the GMP [of claim 19] as an agent against plaque and caries.

APPENDIX B - CURRENT CLAIMS

1. A process for the extraction of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material;

separating the resin from the treated liquid material; and

rinsing the resin to obtain the GMP therefrom.

2. The process according to claim 1 wherein the lactic raw material is one of sweet whey obtained after separation of casein coagulated with rennet, a concentrate of sweet whey, a sweet whey or such a whey demineralized to by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of sweet whey demineralized by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of proteins of substantially lactose-free sweet whey obtained by ultrafiltration, followed by diafiltration (ultrafiltration with washing), mother liquors of the crystallization of lactose from sweet whey, a permeate of ultrafiltration of a sweet whey, the product of hydrolysis, by a protease, of a native casein obtained by acid precipitation of skimmed milk with an inorganic acid or by biological acidification, where appropriate with addition of calcium ions or alternatively of a micellar casein, obtained by microfiltration of a skimmed milk, the product of hydrolysis of a caseinate by a protease,

3. The process according to claim 1 wherein the sweet whey has a solids content of about 10 to 23 percent by weight and is completely deionized during the cation removal step.

4. The process according to claim 1 wherein the lactic raw material is a liquid or a dispersion of solids in a liquid and which further comprises adding calcium ions to the lactic raw material after the cation removal step.

5. The process according to claim 1 which further comprises treating the resin with an alkaline material prior to contacting the substantially deionized lactic raw material with the resin.

6. A process for the extraction of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material, wherein the substantially deionized lactic raw material contacts the resin in a gently stirred reactor at a temperature of less than 50°C for one to ten hours to adsorb the GMP onto the resin;

separating the resin from the treated liquid material; and

rinsing the resin to obtain the GMP therefrom.

7. The process according to claim 6 wherein the reactor is at a temperature between 0°C and 15°C and the resin is basic and in macroporous or macrocross-linked gel form.

8. The process according to claim 1 wherein the substantially deionized lactic raw material contacts the resin until the treated liquid material attains a constant pH of between about 4.5 to 5.5.

9. A process for the extraction and removal of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material;

separating the resin from the treated liquid material; and

concentrating the treated liquid material by evaporation and drying.

10. The process according to claim 9 wherein the treated liquid material is dried by spray drying and which further comprises separating the resin from the treated material by filtration or centrifugation prior to evaporation and drying.

11. The process according to claim 1 [further comprising,] wherein the anionic resin and the deionized lactic raw material are present in a [volume] ratio by volume of between [about] 1:1 [to about] and 1:30.

12. The process according to claim 1 which further comprises the steps of:

separating the GMP from the resin by washing the resin with demineralized water to obtain an eluate;

desorbing the GMP from the resin by washing the resin with an acidic, basic or saline aqueous solution rinse;

washing the resin with demineralized water;

combining the eluate and the washings;

demineralizing the combined eluate and washings by ultrafiltration or nanofiltration on a membrane with a mean cut-off region of about 3000 daltons to obtain a retentate and filtrate; and

recovering the GMP as the retentate.

13. The process according to claim 12 wherein, the basic aqueous solution comprises NaOH, KOH or $Ca(OH)_2$, in a concentration of less than 8% wherein the retentate is freeze-dried to recover the GMP.

14. The process of claim 1 wherein the treated liquid material has an amino acid profile is reduced in threonine and enriched in aromatic amino acids and tryptophan relative to the lactic raw material.

15. The process of claim 14 wherein, relative to the lactic raw material, the threonine content is reduced by about 15 to 40%, and the aromatic amino acids and tryptophan are increased by about 20 to 60%.

16. The process of claim 14, wherein the treated liquid material is included in an infant or dietetic product as protein raw material.

17. The process of claim 9 wherein the treated liquid material is included in an infant or dietetic product as protein raw material.

18. The process of claim 10 wherein the dried treated liquid material is included in an infant or dietetic product as protein raw material.

19. The process of claim 1 wherein the GMP obtained therefrom includes less than 1% by weight of fat, less than 0.2% by weight of lactose, and less than 3% by weight of true whey products and is included with a carrier in a composition.

20. The process of claim 19 wherein the composition is a pharmaceutical composition containing the GMP as an antithrombotic, antidiarrheal or antibacterial agents.

21. The process of claim 19 wherein the composition is a food composition containing the GMP as an emulsifying, gelling or foaming agent.

22. The process of claim 19 wherein the composition is a dental composition containing the GMP as an agent against plaque and caries.